**REMARKS**

Claims 11-14, 35-39 and 43-64 presently appear in this case. No claims have been allowed. Claims 14, 39, 45 and 50 have been withdrawn from consideration, but it is understood that in the event that the remaining claims are found allowable, these withdrawn claims will be treated as per MPEP §821.04. It is assumed that the same will be the case for newly-submitted claims 55 and 62. The remaining claims are subject to rejection. The official action of June 6, 2000, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to isolated DNA molecules which encode naturally-occurring human TBP-II or active fragments thereof, as well as replicable expression vehicles capable of expressing that protein, host cells transformed with such replicable expression vehicles, and processes for producing the protein by culturing such host cells. The present invention further relates to DNA encoding fragments of TBP-II which are long enough to serve as DNA probes or which encode fragments of sufficient length to serve as immunogens for raising antibodies.

Claims 11-13, 35-38, 43, 44, 46-49 and 51 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed.

This rejection is the same as the sole rejection previously in this case which was the subject of applicant's

brief on appeal of March 23, 2000. Accordingly, applicant hereby incorporates by reference the entire contents of applicant's brief on appeal of March 23, 2000. The examiner's response to applicant's arguments in the brief on appeal will be set forth in a reply brief after applicant has an opportunity to consider any examiner's answer which is eventually filed by the examiner.

Claims 35-38, 43, 44, 46-49 and 51 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey that the inventors had possession of the claimed invention. The examiner states that there is no support in the specification as originally filed for the claimed DNA molecules encoding the fragment of claim 35, part (2) or claim 36, part (2) or claim 46, part (2) or claim 51, part (2). The examiner states that there is no disclosure in the specification as originally filed of DNA molecules encoding the aforementioned fragments recited in the claims, and, therefore, the claimed inventions constitute new matter.

First of all, new claims 52-62 have been submitted which are identical to the rejected claims, except for omission from the claims of specific reference to DNA molecules encoding fragments. Accordingly, these claims should not be subject to this new ground of rejection.

With respect to claims 35-38, 43, 44, 46-49 and 51, it is urged that the reference to DNA encoding active

fragments of TBP-II is sufficiently supported in the present specification to establish that the inventors were in possession of the invention at the time that the application was filed and, therefore, in full compliance with the written description requirement of the first paragraph of 35 U.S.C. §112. As stated in *Nelson v. Bowler*, 1 USPQ2d 2076, 2078 (Bd Pat App & Int'f 1986):

> It is not necessary that the claimed subject matter be described in *ipsis verbis* to satisfy the written description requirement of 35 USC 112.

It is sufficient that the specification "conveys clearly to those skilled in the art, to whom it is addressed, in any way, the information that the applicant has invented the subject matter later claimed." (*In re Wertheim* 191 USPQ 90, 97 (CCPA 1976)). Adequate disclosure may be by any means, since the objective is to communicate the invention to the reader who is skilled in the art. (*Standard Oil Co. v. Montedison, S.p.A.*, 212 USPQ 327, 337-8 (3d Cir. 1981)).

Here the specification as a whole makes it clear to one skilled in the art that the applicants were in possession of the claimed subject matter at the time of filing of the application. It is clear that the specification describes active fractions of the TBP-II protein. Such active fractions are described and defined on page 15, lines 11-17. Further, it is clear that the specification contains written description for DNA sequences "coding for TBP-II or for a protein substantially homologous therewith" (see page 4, lines

16-17). While the term "proteins substantially homologous therewith" is never specifically defined in the specification, those of ordinary skill in the art would expect that those modifications of the TBP protein described in the specification would be considered to be proteins substantially homologous therewith. Reference is made to page 7, lines 18-22, which states:

> The present invention encompasses a protein comprising the above sequence, herein referred to as TBP-II, as well as any other polypeptide in which one or more amino acids in the structure of natural TBP-II are deleted or replaced with other amino acids, or one or more amino acids are added thereto, as long as they have human TBP-II activity.

Those of ordinary skill in the art would understand this to be a description of homologs of TBP-II. This description includes other polypeptides in which one or more amino acids in the structure of natural TBP-II are deleted, as long as they have human TBP-II activity, in other words, active fragments. It is, thus, apparent that such active fragments are understood to be included in the phrase "proteins substantially homologous therewith" and, therefore, there is written description of DNA encoding active fragments of TBP-II.

Furthermore, the specification in several areas specifically refers to DNA encoding fragments of TBP-II, although not necessarily the active fragments described on page 15.

On page 9, lines 13-21, there is a description of a synthetic oligonucleotide whose sequence is derived from the amino acid sequence of a fragment of the protein. Note also page 10, lines 3-5, which states:

> The invention also relates to synthetic oligonucleotides to be used as probes to the DNA coding for TBP-II. They are synthesized by known methods on the basis of the amino acid sequence of fragments of TBP-II.

Another disclosure of DNA encoding fragments of TBP-II appears in the last three lines of page 16, which refers to the fusion of one of the possible nucleotide sequences coding for a fragment of TBP-II to a gene coding for Protein A. While these descriptions of DNA encoding fragments of TBP-II are in a different context from DNA encoding active fragments, it is clear from a consideration of the specification as a whole that, at the time the invention was made, applicants were in possession of DNA encoding fragments of TBP-II; applicants were in possession of active fragments of TBP-II; and applicants were in possession of DNA encoding TBP-II and proteins substantially homologous therewith. The aggregate of these disclosures should be sufficient to establish that the applicants invented DNA encoding active fragments of TBP-II, i.e., that applicants were in possession of the claimed DNA encoding active fragments of TBP-II at the time of the filing of the application. To refuse to permit applicants to claim DNA encoding active fragments of the protein despite a disclosure of the entire protein and active fragments thereof, a disclosure of DNA encoding the protein and proteins

substantially homologous thereto, and disclosure of DNA encoding other fragments of the protein, would be a hypertechnical application of the written description requirement, exalting form over substance. As stated at MPEP §2163. :

> Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 111, 117 (Fed Cir 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." [emphasis added]

It is, thus, clear that there is a requirement for reasonableness. The conveyance must be with reasonable clarity and the specification must reasonably convey that applicant was in possession of the invention. For the reasons discussed above, the present disclosure reasonably conveys this fact with reasonable clarity. Reconsideration and withdrawal of this rejection are, therefore, respectfully urged.

New claims 63 and 64 have now been added drawn to DNA encoding other fragments of TBP-II which are described in the specification. The first relates to oligonucleotide probes. This language is supported by the specification at page 9, line 13, through page 11, line 10. Regardless of

whether there is written description for DNA encoding active fragments, there is clearly written description for DNA encoding synthetic oligonucleotide probes whose sequence is derived from the amino acid sequence of a fragment of TBP-II. Those of ordinary skill in the art at the time the invention was made were clearly aware of the size requirements for oligonucleotide probes designed to isolate and identify proteins. With respect to claim 64, this claim is supported by the paragraph bridging pages 16 and 17 of the specification.

It is submitted that all of the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are, therefore, earnestly solicited.

Respectfully submitted,

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